

### **REMARKS**

This amendment is being filed in response to the Office Action mailed August 7, 2003 having a shortened statutory response period ending on November 7, 2003. This response is filed within the statutory response period. The Commissioner is hereby authorized to charge any additional fees to Deposit Account No. 02-1818. Applicants respectfully request reconsideration and allowance of the pending claims in the present application in view of the foregoing amendments and remarks below.

#### **1. Elections/Restrictions**

Applicants hereby affirm the election without traverse to prosecute the invention of Group II, claims 29-35.

#### **2. Status of the Claims**

Claims 29-30, 33-52 are currently pending in the application. Claims 1-28 have been withdrawn. Claims 31 and 32 have been canceled. Claims 29 and 33-35 have been amended. New claims 36-52 have been added. Support for these amendments and new claims is found in the application as follows:

- claim 29 page 10 line 31 through page 11 line 11;
- claim 34, page 11 lines 2-4;
- claim 35, page 10 line 31 through page 11 line 11, page 13 line 14 through page 16 line 35;
- claim 36, page 11 lines 12-20;
- claim 37, page 10 lines 5 through 30;
- claim 38, page 10 lines 27-30;
- claim 39, page 10 line 31 through page 11 line 2;
- claims 40-41 and 49, page 12 lines 8-14;
- claim 42, page 15 lines 14-22;
- claim 43, page 14 line 30 through page 15 line 4;
- claims 44-45 and 51-52, page 15 lines 5-13;
- claims 46-48, page 12 line 21 through page 13 line 12, FIG. 3; and
- claim 50, page 12 line 31 through page 13 line 13.

### 3. §112 Rejections

Claims 29-35 were rejected under 35 U.S.C. §112 2<sup>nd</sup> paragraph as the phrase "the sterile water for injection syringe meets the requirements of the United States Pharmacopoeia for sterile water injection" in claims 29 and 35 was considered indefinite. This phrase has been removed from claims 29 and 35. Applicants respectfully request that the §112 rejections be withdrawn.

### 4. Prior Art Rejections

Claims 29 and 35 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,620,425 to Heffernan et al. (*Heffernan*). Claims 30-32 were rejected under 35 U.S.C. § 103(a) as being obvious over Heffernan in view of the Applicant's Admitted Prior Art (AAPA). Claim 33 was rejected under 35 U.S.C. § 103(a) as being obvious over *Heffernan* in view of the AAPA in further view of U.S. Patent No. 4,978,714 to Bayan et al. (*Bayan*).

*Heffernan*, *Bayan* or the AAPA, either alone or in combination, contain no teaching or suggestion of applying a sterilant to the sterilized syringe body while transferring the syringe body to a sterile environment as recited in claims 29, 35 or 46, for example. *Heffernan* merely discloses that the syringe components are placed in a clean, heat-sealed bag prior to use. *Heffernan*, col. 6 lines 12-20. Consequently, *Heffernan* has no disclosure whatsoever directed to applying a sterilant to the syringe components during transfer to a sterile environment. Similarly, *Bayan* has no disclosure whatsoever pertaining to the applying a sterilant to the syringe components during transfer to a sterile environment as *Bayan* merely discloses that syringe tips may be made out of chlorobutyl rubber. *Bayan*, col. 5 lines 15-24, col. 7 lines 23-30.

Moreover, *Heffernan* teaches away from providing a syringe composed of a norbornene and ethylene copolymer as recited in claims 29, 35 and 47, for example. Rather, *Heffernan* discloses that the syringe barrel is composed of polyolefin polymers and copolymers such as polypropylene, and methylpentene. *Heffernan*, col. 4 lines 42-47; col. 5 lines 60-61. The skilled artisan would readily recognize that such polyolefin polymers are non-cyclic thereby teaching away from the recited cyclic norbornene and ethylene copolymer. In addition, *Heffernan*, *Bayan* and the AAPA have no disclosure

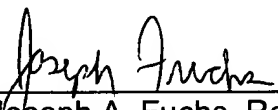
whatsoever regarding maintaining the sterilized water at a pH of about 5.0 to about 7.0 for a predetermined time as recited in claims 35 and 50-52, for example.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 29-30 and 33-52 are in condition for allowance and respectfully request early notice thereof.

Respectfully submitted,  
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